



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,268	02/06/2001	Joseph Gross	E1067/20025	5215

3000 7590 05/20/2004
CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOV, LTD.
12TH FLOOR, SEVEN PENN CENTER
1635 MARKET STREET
PHILADELPHIA, PA 19103-2212

EXAMINER

COMPTON, ERIC B

ART UNIT PAPER NUMBER

3726

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/778,268	GROSS ET AL.	
	Examiner	Art Unit	
	Eric B. Compton	3726	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-18 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-18 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 16-17 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of JP 63-207546 to Saito et al (SAITOU IKA KOGYO KK).

Saito et al disclose a method of forming hypodermic needles (see Figure 6) comprising arranging a plurality of shafts (15) in a row parallel with one another and (see Figure 1) and running a grinding stone (12) across the row of shafts (15) to create a traverse aperture (12a) across the plurality of shafts. "To aim at improvement in work efficiency, by tilting a work aggregate of hypodermic needles, etc. ... [by] grinding a grinding groove by the stone." JPO English Abstract. Since, the shaft is to become a hypodermic needle it is inherent that a bore is to be formed within the shaft either before or after the after process, although not expressly disclosed.

Regarding claim 16, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have arranging a plurality of shafts having a bore in a row parallel with one another and performing the shaft opening across the row of shafts, in light of the teachings of Saito et al, in order to increase efficiency by grinding a plurality of shaft in one operations and to obviate the need to form bores individually in the needles after the grinding. JPO English Abstract of Saito et al.

Art Unit: 3726

Regarding claim 25, the shaft opening operations of Saito et al can be considered a machining operation (i.e., material removing processes).

Regarding claim 17, Saito et al disclose the machining operation comprises running a grinder across the row of shafts to grind a line of the apertures across the external surfaces of the shafts. Figures 1-5.

3. Claims 16-17 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of U.S. Pat. 5,425,376 to Banys et al in view of JP 63-207546 to Saito et al (SAITOU IKA KOGYO KK).

Banys et al discloses a needle (14) for delivery of a flowable material (see Col. 5, lines 38-39) having a shaft (16) with an internal bore and an external surface including a side portion having an aperture (28) in communication with the bore of the shaft.

Needle 16 is a hollow steel tube having a solid or plugged distal end 26, which is cut at an angle to provide a sharp edge or point for ease of entry into the sample area. Lateral opening 28 is formed in the wall of needle 16, preferably near the distal end 26 of needle 16. Lateral opening 28 is formed with at least one sharp cutting edge 27 near the distal end of opening 28, to assist in the cutting of a sample from the selected tissue.

Col. 5, lines 1-8. Banys et al suggest some machining tool is used to form the lateral cutting edge (28) with the at least one sharp cutting edge (27).

However, Banys et al does not suggest arranging a plurality of shafts in a row parallel with one another and performing the shaft opening across the row of shafts.

Saito et al disclose a method of forming hypodermic needles (see Figure 6) comprising arranging a plurality of shafts (15) in a row parallel with one another and (see Figure 1) and running a grinding stone (12) across the row of shafts (15) to create a traverse aperture (12a) across the plurality of shafts. Since, the shaft is to become a

Art Unit: 3726

hypodermic needle it is inherent that a bore is to be formed within the shaft either before or after the after process, although not expressly disclosed.

Regarding claim 16, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have formed the needle of Banys et al by arranging a plurality of shafts in a row parallel with one another and performing the shaft opening across the row of shafts, in light of the teachings of Saito et al, in order to increase efficiency by grinding a plurality of shaft in one operations. JPO English Abstract of Saito et al.

Regarding claim 25, the shaft opening operations of Saito et al can be considered a machining operation (i.e., material removing processes).

Regarding claim 17, Saito et al disclose the machining operation comprises running a grinder across the row of shafts to grind a line of the apertures across the external surfaces of the shafts. Figures 1-5.

4. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al either alone or in combination with Banys et al as applied to claim 16 above, and further in view of U.S Patent 2,802,310 to Chaplik.

Saito et al either alone or in combination with Banys et al disclose the invention cited above. Both references show an inclined tip on the needle. It is inherent that the tip of the needle is used to puncture or pierce through tissue, thus it inherently must be sharp. However, they do not disclose sharpening the needle while they are arranged parallel in a row.

Chaplik discloses a method and apparatus for grinding the tip of a hypodermic needle with a grinding wheel to sharpen it.

Regarding claim 18, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have sharpened the shafts of Saito et al either alone or in combination with Banys et al, while they were arranged in a row, in order to sharpen all of the tips of the needles to provide a clean slit with inserted into tissue. Chaplik, Col. 1, lines 39-44. Again, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have performed the sharpening process while the shafts are arranged parallel in a row in order to increase efficiency. JPO English Abstract of Saito et al.

Response to Arguments

5. Applicant's arguments filed April 13, 2004, have been fully considered.
6. Applicant is correct in pointing out that the effective filing date of the instant invention precedes the prior art date of GB 2298368 to Cockburn. Therefore, rejections based on Cockburn have been withdrawn.
7. Applicant's arguments with respect to claims 16-18 and 25 have been considered but are moot in view of the new ground(s) of rejection. Applicant did not address the Saito et al reference and its teachings, which discloses the crux of Applicant's invention. See also Banys et al, which discloses a needle having the same structural limitations as Applicant's invention.

Prior Art References

The prior art references listed on the enclosed PTO-892, but not used in a rejection of the claims, are cited for their teachings of forming needles.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric B. Compton whose telephone number is (703) 305-0240. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter B. Vo can be reached on (703) 308-1789. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric Compton
Patent Examiner